Section 5: 510(k) Summary

Device Information:

Category	Comments
Sponsor / Submitter:	Myoscience, Inc 525 Chesapeake Drive Redwood City, CA 94063 (650) 474-2600 (650) 474-2700
Correspondent Contact Information:	Tracey Henry Vice President RAQA, Clinical Compliance 525 Chesapeake Drive Redwood City, CA 94063 (650) 474-2600 (650) 474-2900
Device Common Name:	Cryogenic Surgical device
Device Classification & Code:	Class II, GXH
Device Classification Name:	Cryosurgical unit and accessories (21 CFR 882.4250)
Device Proprietary Name:	Myoscience Cryo-Touch III

a. Predicate Device Information:

The Cryo-Touch III is substantially equivalent to the following currently legally marketed devices:

510(k) Number	Product	Sponsor
K083493	Cryo-Touch	Myoscience, Inc
K102021	Cryo-Touch II	Myoscience, Inc

b. Date Summary Prepared

February 8, 2012

c. Description of Device

The Myoscience Cryo-Touch III is a portable cryogenic surgical device used to destroy tissue and/or produce lesions in nervous tissue through application of extreme cold to the selected site. The device is based on introduction of a needle probe, "Tip" cooled by the cryogenic fluid (liquid nitrous oxide, N_2O) to a selected area. The Tip is cooled by the Joule-Thomson effect and/or Latent Heat of Vaporization. The Cryo-Touch III may be used in conjunction with a standard off-the-shelf nerve stimulator device in applications where precise nerve location is desired.

Device Design

The device is comprised of four main components:

1. a re-usable Control Unit,
2. a re-usable Handpiece,
3. a single patient use Tip, and

Test Performed	Result
Temperature reproducibility	PASS, Substantially equivalent to predicate
Mechanical Integrity for system	PASS, Substantially equivalent to predicate
Disable valve reliability	PASS, Substantially equivalent to predicate
Thermal fuse testing	PASS, Substantially equivalent to predicate
Nitrous exposure	PASS, Substantially equivalent to predicate
Cryozone size	PASS, Substantially equivalent to predicate
Needle Integrity	PASS, Substantially equivalent to predicate
Device Durability	PASS, Substantially equivalent to predicate
Sterilization and Shelf Life Testing	PASS, Substantially equivalent to predicate
Electrical Safety Testing	PASS, Substantially equivalent to predicate
Software Testing	PASS, Substantially equivalent to predicate
Safety Testing	PASS, Substantially equivalent to predicate
Biocompatibility Testing	PASS, Substantially equivalent to predicate

This performance testing demonstrated that the device is in compliance with pertinent standards (IEC 60601-1, IEC 60601-1-2, ISO 10993-1, ISO 11137-1, ISO 11607, and ASTM F882-84), the product labeling, and is substantially equivalent to the predicates.

Clinical Testing Submitted: None

g. Conclusion

Myoscience concludes that the Cryo-Touch III described in this submission is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MyoScience, Incorporated
% Ms. Tracey Henry
Sr. Director, Regulatory Affairs and Quality Assurance
525 Chesapeake Drive
Redwood City, CA 94063

JUN 22 2012

Re: K120415
Trade/Device Name: Myoscience Cryo-touch III
Regulation Number: 21 CFR 882.4250
Regulation Name: Cryogenic Surgical Device
Regulatory Class: II
Product Code: GXH
Dated: June 13, 2012
Received: June 15, 2012

Dear Ms. Henry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
Office of Device Evaluation Health
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number:

Device Name:
Myoscience Cryo-Touch III

Indications for Use:

The Myoscience Cryo-Touch III is used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. The Cryo-Touch III is not indicated for treatment of central nervous system tissue.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daryl L Kaufman

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K120415